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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,282	04/01/2004	Tilak M. Shah	4179-128	8353
23448	7590	10/13/2005	EXAMINER	
INTELLECTUAL PROPERTY / TECHNOLOGY LAW PO BOX 14329 RESEARCH TRIANGLE PARK, NC 27709			TRAN, THAO T	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/815,282

Applicant(s)

SHAH, TILAK M.

Examiner

Thao T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 36-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/29/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-35, drawn to a multilayer film, classified in class 428, subclass 411.1.
  - III. Claims 36-40, drawn to a method of therapeutic intervention, classified in class 600, subclass 116.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a different method, such as coating an article with a layer containing the product.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Mr. Steven Hultquist on October 5, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-35.

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Affirmation of this election must be made by applicant in replying to this Office action. Claims 36-40 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Michaels et al. (US Pat. 3,901,232).

Michaels discloses a drug delivery means 14, comprising a deformable member 16 having a wall made of laminate of polyurethane and polyvinylidene chloride. The layers can be about 0.4-20 mil thick (see abstract; Figs. 1-3; col. 3, ln. 25-32; col. 4, ln. 60-65; col. 6, ln. 4-19).

The deformable member contains compounds that change to a gas at physiological temperature (see col. 7, ln. 6-25).

8. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell et al. (US Pat. 5,713,141).

Mitchell discloses a gas-filled bladder, comprising a flexible membrane of at least one flexible thermoplastic layer 32 and at least one gas barrier layer 30 (see abstract; Figs 1-5; col. 8, ln. 4-6). The thermoplastic layer comprises thermoplastic urethane, whereas the gas barrier layer comprises polyvinylidene chloride or ethylene vinyl alcohol copolymer (see col. 9, ln. 1-45).

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The thickness of the thermoplastic layer is between about 0.005-0.05 in (0.127-1.27 mm) and the thickness of the gas barrier layer is about 0.0025-0.005 in (0.0635-0.127 mm) (see claim 11).

9. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonk et al. (US Pat. 6,082,025).

Bonk discloses a bladder membrane comprising at least two layers, a first layer of a thermoplastic elastomer, such as a thermoplastic polyurethane, and a second layer including a barrier material, such as a copolymer of ethylene and vinyl alcohol (see col. 3, ln. 53-62; col. 4, ln. 17-22). The membrane may also comprise different layers of the barrier material and different layers of the thermoplastic elastomer (see paragraph crossing col. 6 & 6). Each individual layer can be about 0.01 mm on the average (see col. 7, ln. 23-24).

The bladder membrane can be a membrane of a catheter balloon (see col. 21, ln. 12-13).

10. Claims 1-8, 10-11, 13-28, 30-31, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al. (US Pat. 5,738,657).

Bryant discloses a bladder member comprising a bladder portion and a sleeve portion; wherein the bladder portion comprises a gas barrier means containing liquid and a gas generating reactive chemical means. The gas barrier means comprises a laminate of a polyurethane layer 58 and a polyvinylidene chloride layer 56. The polyvinylidene chloride layer is 1 mil whereas the polyurethane layer is 20 mil or 10 mil (see Figs. 10-12; col. 8, ln. 41-50; col. 9, ln. 9-16).

The gas barrier means can be sealed balloon 50 containing sodium carbonate that release carbon dioxide upon contact with water (see paragraph crossing col. 4 & 5; col. 8, ln. 8-12).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 9, 12, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant as applied to claims 1 and 20 above.

Bryant is as set forth in claims 1 and 20 above and incorporated herein.

Bryant does not teach the multilayer to be about 2-6 mil or the polyurethane layer to be about 2.0-5.0 mil thick. However, the reference teaches the polyvinylidene chloride layer to be 1 mil and the polyurethane layer to be 10 mil or 20 mil.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention as made, that the thickness of a layer would have been determined by routine optimization and would have been adjusted to a desired thickness, depending upon user's preference and intended use.

***Contact Information***

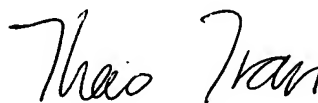
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thao T. Tran whose telephone number is 571-272-1080. The examiner can normally be reached on Monday-Friday, from 9:00 a.m. - 5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tt  
October 6, 2005



**THAO T. TRAN**  
**PATENT EXAMINER**